



PATENT  
Attorney Docket No. MTP-024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13

APPLICANT(S): Watkins *et al.*  
SERIAL NO.: 09/709,947 GROUP NO.: 1642  
FILING DATE: November 10, 2000 EXAMINER: A. Harris, Ph.D.  
TITLE: Materials and Methods for Detection and Treatment of Breast  
Cancer

Box DAC  
Commissioner for Patents  
Washington, D.C. 20231

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NOV 19 2002

PETITION UNDER 37 C.F.R. § 1.181  
TO WITHDRAW HOLDING OF ABANDONMENT

TECH CENTER 1600/2900

Sir:

Applicants hereby petition under 37 C.F.R. § 1.181 that the holding of abandonment of this application be reconsidered and withdrawn. This petition is responsive to the Notice of Abandonment mailed from the U.S. Patent and Trademark Office on October 2, 2002. Applicants submit that the petition is being filed within two months of the mailing date of the Notice of Abandonment, and therefore is timely as provided by 37 C.F.R. § 1.181(f).

An Office action, including a requirement for restriction, was mailed from the U.S. Patent and Trademark Office on March 26, 2002. A copy of the Office action is attached as Exhibit A. The Office action set a one month shortened statutory period for reply.

According to the Notice of Abandonment (attached as Exhibit B), no reply to the Office action was received.

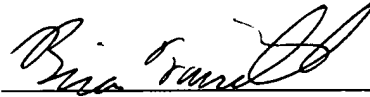
On September 26, 2002, Applicants had indeed responded to the Office action. Applicants included with the response a petition for a five-month extension of time under 37 C.F.R. § 1.136(a) extending the available time for response up to and including September 26, 2002, a check in the amount of \$980.00 (listed on the return receipt postcard incorrectly as in the amount of \$890.00), and a signed authorization to charge any additional fees which may have been required to Deposit Account No. 20-0531. Applicants' response and the accompanying papers (collectively, "the Response," including a transmittal form, an amendment and response to the Office action, a marked-up copy of the amended claims, the petition and check for the five-month extension of time, and a return receipt postcard, copies of which are attached as Exhibit C) were sent to the Commissioner for Patents, Washington, DC 20231 utilizing the "Express Mail Post Office to Addressee" service of the U.S. Postal Service on September 26, 2002. Applicants enclose as Exhibit D a copy of the "Express Mail" mailing label, showing a "date-in" of "9-26-02," and a date stamp of "SEP 26 2002." Furthermore, the Response was received by the U.S. Patent and Trademark Office, as evidenced by the enclosed copy of the return receipt postcard (see Exhibit C), date-stamped by OIPE as "SEP 26 2002."

Accordingly, Applicants submit that the Response to the Office action of March 26, 2002, was timely filed: the Response was received by the U.S. Patent and Trademark Office, was properly accorded its date of deposit with the U.S. Postal Service, September 26, 2002, under 37 C.F.R. § 1.10(a), and was accompanied by a petition and fee for a five-month extension of time. Accordingly, Applicants respectfully request that the holding of abandonment be reconsidered and withdrawn, and that the application be examined under 37 C.F.R. § 1.104.

Applicants believe no fee is required for consideration of this petition under 37 C.F.R. § 1.181. Nevertheless, please charge any required fee to Deposit Account No. 20-0531.

The Office is invited to contact the undersigned with any questions.

Respectfully submitted,



---

Brian Fairchild  
Agent for the Applicants  
Testa, Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110

Date: November 14, 2002  
Reg. No. 48,645  
Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7970

2519257



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,947	11/10/2000	Brynmor Watkins	MTP-024	3918

21323 7590 03/26/2002

TESTA, HURWITZ & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON, MA 02110

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EXAMINER

HARRIS, ALANA M

MAR 29 2002

ART UNIT

PAPER NUMBER

1642

8

PATENT DEPARTMENT DATE MAILED: 03/26/2002  
TESTA, HURWITZ & THIBEAULT, LLP

Please find below and/or attached an Office communication concerning this application or proceeding.

**DOCKETED** Response DueBase Date: 3-26-02Due Date: 4-26-02Statutory Period: 9-26-02Administrator: KASDate: 4-1-02

Reviewed &amp; Approved:

Resp. Atty

Date

APP. COPY

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/709,947		WATKINS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Alana M. Harris, Ph.D.		1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input checked="" type="checkbox"/> Other: See Continuation Sheet.       |

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY  
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 10% OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

THE DOCUMENT(S) ACCOMPANYING THIS FACSIMILE TRANSMISSION CONTAIN(S) INFORMATION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE WHICH IS CONFIDENTIAL AND/OR LEGALLY PRIVILEGED. THIS INFORMATION IS FOR THE USE OF THE INDIVIDUAL OR FIRM NAMED ON THIS SHEET. IF YOU ARE NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, COPYING, DISTRIBUTION, OR THE TAKING OF ANY ACTION IN RELIANCE ON THE CONTENTS OF THIS INFORMATION IS STRICTLY PROHIBITED. THE DOCUMENTS SHOULD BE RETURNED TO THE PATENT AND TRADEMARK OFFICE IMMEDIATELY. IF THIS FACSIMILE IS RECEIVED IN ERROR, PLEASE NOTIFY THE ATTORNEY LISTED HEREON IMMEDIATELY.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to an isolated breast cancer-associated polypeptide, classified in class 530, subclass 350.
  - II. Claims 9-14 and 43-47, drawn to a method of diagnosing cancer comprising detecting the presence of a polypeptide, classified in class 435, subclass 7.1.
  - III. Claims 15-20, 41, 42 and 48-55, drawn to a method of diagnosing cancer comprising contacting a sample with a binding moiety, classified in class 436, subclass 512.
  - IV. Claims 21-24, drawn to an isolated binding moiety, classified in class 530, subclass 387.1.
  - V. Claims 25 and 26, drawn to a method of treating cancer comprising administering a binding moiety, classified in class 514, subclass 2.
  - VI. Claims 27-31, drawn to an isolated nucleic acid sequence, classified in class 536, subclass 23.1.
  - VII. Claims 32 and 33, drawn to a method of treating cancer comprising introducing into cells a nucleic acid, classified in class 514, subclass 44.
  - VIII. Claims 34-40 and 56-62, drawn to a method of detecting the presence of breast cancer comprising detecting a nucleic acid molecule, classified in class 435, subclass 6.



2. The inventions are distinct, each from the other because of the following reasons:

Groups I, IV and VI are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups II, III, V, VII and VIII differ in the method objectives, method steps and parameters and in the reagents used. Furthermore, Groups II, III and VIII are *in vitro* diagnostic assays, whereas method groups of inventions V and VII read on *in vivo* processes.

Inventions IV and II, III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody product of Group IV can be used in any of the methods of Groups II, III and V.

Inventions VI and VII and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group VI can be used in either method of Groups VII or VIII.

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3. Groups II, III and VIII drawn to methods detecting polypeptide sequences selected from the group consisting of SEQ ID NO:1-23. Each polypeptide sequence is a structurally different product comprised of different amino acid residues and the examination of more than one sequences would result in an undue search burden on the PTO. **Thus, with the election of any of one of Groups II, III or VII, the applicant is required to select one sequence from the following twenty-three sequences: SEQ ID NO:1-23 for examination.**

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. A telephone call was made to Duncan A. Greenhalgh on March 18, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 1642

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.



Alana M. Harris, Ph.D.  
March 16, 2002



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/709,947

11/10/2000

Brynmor Watkins

MTP-024

3918

21323

7590

10/02/2002

TESTA, HURWITZ & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON, MA 02110

EXAMINER
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HARRIS, ALANA M.

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 10/02/2002



Please find below and/or attached an Office communication concerning this application or proceeding.

**Notice of Abandonment**

Application No.

09/709,947

Examiner

Alana M. Harris, Ph.D.

Applicant(s)

WATKINS ET AL.


Art Unit

1642

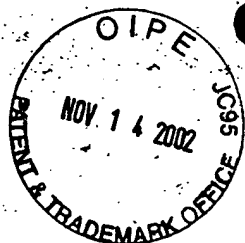
**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 26 March 2002.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



MTP-024  
(8395/33)

The "RECEIVED" stamp of the Patent Office imprinted hereon acknowledges the filing of:

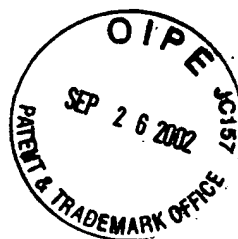
Transmittal Form (1 pg.); Amendment and Response to Restriction Requirement (5 pgs.); Marked-Up Copy of Amended Claims (2 pgs.); Petition For Extension of Time Under 37 CFR 1.136(a) (Five Month Extension of Time) (1 pg.); and check in the amount of \$890.00, each paper and fee bearing Express Mail Mailing Label No. EL953993705US thereon.

Name of Applicant: Watkins et al.

Invt. or Serial Number: 09/709,947

Atty: DAGreenhalgh/BAFairchild

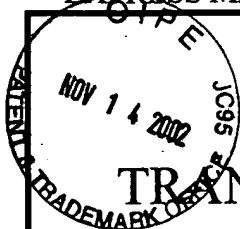
Date: September 26, 2002



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TECH CENTER 1600/2900



# TRANSMITTAL FORM

Application Serial Number	09/709,947
Filing Date	November 10, 2000
First Named Inventor	Watkins et al.
Group Art Unit	1642
Examiner Name	A. Harris
Attorney Docket No.	MTP-024
Patent No.	Not applicable
Issue Date	Not applicable

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form  <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]  <input checked="" type="checkbox"/> Petition for Extension of Time  <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Form PTO-1449 <input type="checkbox"/> Copies of IDS Citations  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)  <input type="checkbox"/> Formal Drawing(s)  <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal  <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application  <input type="checkbox"/> Small Entity Statement  <input type="checkbox"/> CD(s) for large table or computer program  <input type="checkbox"/> Amendment After Allowance  <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences  <input type="checkbox"/> Appeal Brief (in triplicate)  <input type="checkbox"/> Status Inquiry  <input checked="" type="checkbox"/> Return Receipt Postcard  <input type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8  <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8  <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below)  Amendment and Response to Restriction Requirement (5 pgs.); and  Marked-Up Copy of Amended Claims (2 pgs.)
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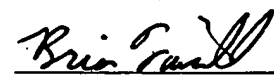
## CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110  
 Tel. No.: (617) 248-7000  
 Fax No.: (617) 248-7100

## SIGNATURE BLOCK

Date: September 26, 2002  
 Reg. No. 48,645  
 Tel. No.: (617) 248-7697  
 Fax No.: (617) 248-7100

Respectfully submitted,

  
 Brian A. Fairchild  
 Agent for Applicant(s)  
 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110

THE FACE OF THIS DOCUMENT HAS A COLORED BACKGROUND ON WHITE PAPER

EXPRESS MAIL MAILING LABEL NO. 6695399370545

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5-39110

Date:

September 25, 2002

212547

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Testa, Hurwitz & Thibault, LLP



ORDER OF: Director of U.S. Patent & Trademark Office

03507 041104 947

0118-0841 03951331

SECURITY FEATURES INCLUDED. DETAILS ON BACK.

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EXPRESS MAIL MAILING LABEL NO. EL953993705US

PATENT  
Attorney Docket No. MTP-024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Watkins *et al.*  
SERIAL NO.: 09/709,947 GROUP NO.: 1642  
FILING DATE: November 10, 2000 EXAMINER: A. Harris, Ph.D.  
TITLE: Materials and Methods for Detection and Treatment of Breast Cancer

Commissioner for Patents  
Washington, D.C. 20231

**AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT**

Sir:

This paper is responsive to the Office action mailed from the U.S. Patent and Trademark Office on March 26, 2002. Applicants enclose a petition and fee to extend the time for response up to and including September 26, 2002.

**AMENDMENT**

Please cancel claims 1-8, 21-40 and 56-62 without prejudice to Applicants' right to pursue their subject matter in this application or in a related application.

Please amend claims 9, 15, and 41 to read as follows:

9. (Amended) A method of diagnosing cancer in an individual comprising detecting in a sample isolated from the individual the presence of a cancer-associated protein of about 28 kD that

(i) binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quaternary ammonium groups and

(ii) elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0, wherein the cancer-associated protein is indicative of cancer in the individual.

15. (Amended) A method of diagnosing cancer in an individual, the method comprising the steps of:

(a) contacting a sample from the individual with a binding moiety that binds specifically to a cancer-associated protein to produce a binding moiety-cancer-associated protein complex, wherein the binding moiety binds specifically to a cancer-associated protein of about 28 kD that (i) binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quaternary ammonium groups and (ii) elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0; and

(b) detecting the complex, which is indicative of the presence of cancer in the individual.

41. (Amended) A kit for detecting the presence of breast cancer or for evaluating the efficacy of a therapeutic treatment of a breast cancer, the kit comprising in combination:

a receptacle for receiving a tissue or body fluid sample from a mammal;

a binding moiety which binds specifically to a breast cancer-associated protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1; SEQ ID NO: 2; SEQ ID NO: 3; SEQ ID NO: 4; SEQ ID NO: 5; SEQ ID NO: 6; SEQ ID NO: 7; SEQ ID NO: 8; SEQ ID NO: 9; SEQ ID NO: 10; SEQ ID NO: 11; SEQ ID NO: 12; SEQ ID NO: 13; SEQ ID NO: 14; SEQ ID NO: 15; SEQ ID NO: 16; SEQ ID NO: 17; SEQ ID NO: 18; SEQ ID NO: 19; SEQ ID NO: 20; SEQ ID NO: 21; SEQ ID NO: 22; and SEQ ID NO: 23;

a means for detecting the binding moiety bound to the breast cancer-associated protein; and

a reference sample.

### REMARKS

Upon entry of this paper, claims 1-8, 21-40 and 56-62 are cancelled without prejudice to Applicants' right to pursue their subject matter in this application or in a related application. Claims 9 and 15 are rewritten in independent form and have been amended to recite that the protein is about 28 kD, binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quarternary ammonium groups, and elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0. Support for the amendment to claims 9 and 15 can be found throughout the application as filed and at least at pages 34-37. Claim 41 has been rewritten in independent form and amended to recite a protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1-23. Support for the amendment to claim 41 can be found throughout the application as filed, and at least in the sequence listing and in originally-filed claim 43. Applicants enclose a marked-up copy of the amended claims in accordance with 37 C.F.R. § 1.121(c)(1)(ii). Applicants submit no new matter has been added by these amendments.

Claims 9-20 and 41-55 are pending.

#### ***Requirement to restrict***

The Office Action alleges that the previously pending claims defined eight patentably distinct inventions, including: Group I, claims 1-8; Group II, claims 9-14 and 43-47; Group III, claims 15-20, 41, 42, and 48-55; Group IV, claims 21-24; Group V, claims 25 and 26; Group VI, claims 27-31; Group VII, claims 32 and 33; and Group VIII, claims 34-40 and 56-62. Applicants have cancelled without prejudice all claims from

Groups I, IV, V, VI, VII, and VIII, obviating the restriction requirement with respect to those claims. Thus, only claims corresponding to Groups II and III remain.

Applicants provisionally elect, with traverse, Group II, including claims 9-14 and 43-47.

Applicants respectfully traverse the restriction requirement as applied to Groups II and III. "If the search and examination of [both sets of claims] can be made without serious burden, the examiner must examine [them] on the merits, even though [the] claims [are] to independent or distinct inventions" (MPEP § 803.01). As defined by the Office action, Group II relates to a method of diagnosing cancer comprising detecting the presence of a polypeptide, and Group III relates to a method of diagnosing cancer comprising contacting a sample with a binding moiety. Applicants submit that one method of detecting the presence of a polypeptide involves the use of a binding moiety, for example, an antibody. Accordingly, Applicants submit that a search and examination of the invention of Group II (detection of a polypeptide) includes a search of art relevant to Group III (contacting a sample with a binding moiety). Applicants therefore request reconsideration of the restriction requirement as applied to Groups II and III, and request rejoinder of the claims of Groups II and III into a single Group.

***Election of species***

To the extent that Applicants elect Group II, III, or VIII, the Office action also requires election of one polypeptide sequence for use in the elected method claims. Applicants provisionally elect, with traverse, the sequence of SEQ ID NO:1. Applicants note that SEQ ID NO:1-4 are each subsequences of SEQ ID NO:5, U2 snRNP B".

Applicants further submit that all pending claims are readable on the provisionally elected species. Applicants understand that upon allowance of generic claims corresponding to the elected species, Applicants may claim additional species as provided by 37 C.F.R. § 1.141.

### CONCLUSION

Upon entry of this paper, claims 9, 15 and 41 are amended and claims 1-8, 21-40 and 56-62 are cancelled. Claims 9-20 and 41-55 will remain pending. Group II and SEQ ID NO:1 are hereby provisionally elected with traverse. The Examiner is invited to contact the undersigned to discuss any outstanding issues. Early favorable action is respectfully requested.

Respectfully submitted,

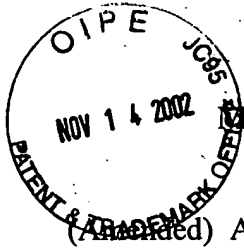


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Date: September 26, 2002  
Reg. No. 48,645  
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Fax No.: (617) 248-7970

2500487



U.S.S.N. 09/709,947

**MARKED-UP COPY OF AMENDED CLAIMS**

9. (Amended) A method of diagnosing cancer in an individual comprising detecting in a sample isolated from the individual the presence of [the polypeptide of claim 1] a cancer-associated protein of about 28 kD that

(i) binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quaternary ammonium groups and

(ii) elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0, [which if present] wherein the cancer-associated protein is indicative of cancer in the individual.

15. (Amended) A method of diagnosing cancer in an individual, the method comprising the steps of:

(a) contacting a sample from the individual with a binding moiety that binds specifically to a cancer-associated protein to produce a binding moiety-cancer-associated protein complex, wherein the binding moiety binds specifically to [the polypeptide of claim 1] a cancer-associated protein of about 28 kD that (i) binds in the presence of 50 mM sodium phosphate, pH 7.0, to an anion exchange resin comprising quaternary ammonium groups and (ii) elutes from the resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0; and

(b) detecting the [presence of the] complex, which [if present] is indicative of the presence of cancer in the individual.

41. (Amended) A kit for detecting the presence of breast cancer or for evaluating the efficacy of a therapeutic treatment of a breast cancer, the kit comprising in combination:

a receptacle for receiving a tissue or body fluid sample from a mammal;

a binding moiety which binds specifically to [the] a breast cancer-associated protein [of claim 1] comprising an amino acid sequence selected from the group


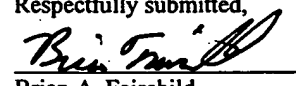
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consisting of SEQ ID NO: 1; SEQ ID NO: 2; SEQ ID NO: 3; SEQ ID NO: 4; SEQ ID NO: 5; SEQ ID NO:6; SEQ ID NO:7; SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; SEQ ID NO:14; SEQ ID NO:15; SEQ ID NO:16; SEQ ID NO:17; SEQ ID NO:18; SEQ ID NO:19; SEQ ID NO:20; SEQ ID NO:21, SEQ ID NO:22; and SEQ ID NO:23;

a means for detecting the binding moiety bound to the breast cancer-associated protein; and

a reference sample.

2500642

<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)</b>		Attorney Docket Number MTP-024																
		In re Application of Watkins et al.																
		Application Serial No. 09/709,947																
		Filed: November 10, 2000																
		Group Art Unit: 1642	Examiner: A. Harris															
<p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response in the above entitled application.</p> <p>The requested extension and appropriate non-small-entity fee are as follows (check time period desired)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"><input type="checkbox"/></td> <td style="width: 70%;">One month (37 CFR 1.17(a)(1))</td> <td style="width: 20%; text-align: right;">\$</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Two months (37 CFR 1.17(a)(2))</td> <td style="text-align: right;">\$</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Three months (37 CFR 1.17(a)(3))</td> <td style="text-align: right;">\$</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Four months (37 CFR 1.17(a)(4))</td> <td style="text-align: right;">\$</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Five months (37 CFR 1.17(a)(5))</td> <td style="text-align: right;">\$ 1,960.00</td> </tr> </table> <p><input checked="" type="checkbox"/> Applicant claims small entity status under 37 CFR 1.27, therefore the fee amount shown above is reduced by one-half, and the resulting fee is: <u>\$980.00</u>.</p> <p><input checked="" type="checkbox"/> A check in the amount of the fee is enclosed.</p> <p><input type="checkbox"/> The Commissioner is hereby authorized to charge the required fee to Deposit Account No. 20-0531. Enclosed is a duplicate of this sheet.</p> <p><input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 20-0531.</p> <p><input checked="" type="checkbox"/> Return receipt postcard enclosed.</p> <p>I am the <input type="checkbox"/> assignee of record of the entire interest.  <input type="checkbox"/> applicant.  <input checked="" type="checkbox"/> attorney or agent of record.  <input type="checkbox"/> attorney or agent under 37 CFR 1.34(a).  Registration number if acting under 37 CFR 1.34(a). _____</p>				<input type="checkbox"/>	One month (37 CFR 1.17(a)(1))	\$	<input type="checkbox"/>	Two months (37 CFR 1.17(a)(2))	\$	<input type="checkbox"/>	Three months (37 CFR 1.17(a)(3))	\$	<input type="checkbox"/>	Four months (37 CFR 1.17(a)(4))	\$	<input checked="" type="checkbox"/>	Five months (37 CFR 1.17(a)(5))	\$ 1,960.00
<input type="checkbox"/>	One month (37 CFR 1.17(a)(1))	\$																
<input type="checkbox"/>	Two months (37 CFR 1.17(a)(2))	\$																
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<input type="checkbox"/>	Four months (37 CFR 1.17(a)(4))	\$																
<input checked="" type="checkbox"/>	Five months (37 CFR 1.17(a)(5))	\$ 1,960.00																
<b>CORRESPONDENCE ADDRESS</b>		<b>SIGNATURE BLOCK</b>																
Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thibault, LLP High Street Tower 125 High Street Boston, MA 02110 Tel. No.: (617) 248-7000 Fax No.: (617) 248-7100		Date: September 26, 2002 Reg. No. 48,645 Tel. No.: (617) 248-7697 Fax No.: (617) 248-7100  Respectfully submitted,  Brian A. Fairchild Agent for Applicant(s) Testa, Hurwitz & Thibault, LLP High Street Tower 125 High Street Boston, MA 02110																

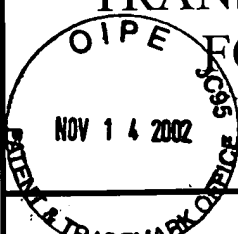




11-15-02

CP/1642

## EXPRESS MAIL MAILING LABEL NO. EL953993740US

<b>TRANSMITTAL FORM</b> 	Application Serial Number	09/709,947 ✓
	Filing Date	November 10, 2000
	First Named Inventor	Watkins
	Group Art Unit	1642
	Examiner Name	A. Harris, Ph.D.
	Attorney Docket No.	MTP-024
	Patent No.	Not applicable
	Issue Date	Not applicable

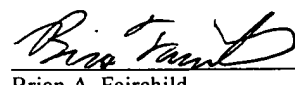
## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____] <input type="checkbox"/> Petition for Extension of Time <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Form PTO-1449 <input type="checkbox"/> Copies of IDS Citations <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553) <input type="checkbox"/> Formal Drawing(s) <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> CD(s) for large table or computer program <input type="checkbox"/> Amendment After Allowance <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences <input type="checkbox"/> Appeal Brief (in triplicate) <input type="checkbox"/> Status Inquiry <input checked="" type="checkbox"/> Return Receipt Postcard <input type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8 <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below) Petition Under 37 C.F.R. § 1.181 To Withdraw Holding of Abandonment (3 pgs.) and Exhibits A-D <div style="text-align: center;"> <b>RECEIVED</b>  <b>NOV 19 2002</b>  <b>TECH CENTER 1600/2900</b> </div>
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## SIGNATURE BLOCK

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